REMARKS

The above-captioned patent application has been carefully reviewed in light of the final Office Action to which this Amendment is responsive. Claims 90 and 104 have been amended in an effort to better clarify and particularly point out that which is regarded as the invention. To that end, it is believed no new subject matter has been added to the above-captioned application.

Claims 90 and 94-106 are pending in the present application. Each of the pending claims have been rejected on the same grounds noted in the preceding Office Action. More particularly, Claims 90, 94, 97 and 103 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Hanna (U.S. Patent No. 6,450,966B1) in view of Roeher (U..S. Patent No. 6,579,241B2); Claims 95-96 and 101-102 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Hanna and Roeher and further in view of Halpern et al. (U.S. Patent No. 5,687,717); and Claims 98-100 and 104-106 have been rejected under 35 U.S.C. §103(a) based on Hanna, Roeher and further in view of Weiner et al. (U.S. Patent No. 6,988,989B2). Applicant again respectfully traverses the above rejections based on the amended claims, as well as the following discussion.

Applicant gratefully acknowledges the telephonic interview granted by Examiner Michael Astorino to Applicant's representative, Peter J. Bilinski, on September 14, 2007. The subject matter of that interview is included in the text of this correspondence.

Applicant would again like to briefly discuss the novel contributions made by the present invention. To that end, a diagnostic workstation is provided that includes an assemblage that further includes a computing device as well as at least one medical device, which can be connected to a patient in order to take physiological readings. In one version, the at least one medical device is a sphygmomanometer that permits blood pressure readings to be taken selectively. The sphygmomanometer includes an inflatable cuff as well as a pressure control assembly that is linked to the computing device of the workstation. The computing device has stored within its memory a plurality of previous blood pressure readings taken from the patient and to that end performs a trend analysis in which a range of "normal" blood pressure readings are established; that is, normal for the patient, as some patients are hypotensive and others are hypertensive and have their

own individual ranges of "normal" readings. In this light, the pressure control assembly automatically inflates to a predetermined inflation pressure for purposes of conducting a blood pressure measurement, as might be set through a schedule based on discrete time intervals (for example, 30 minutes, 20 minutes, etc). Prior to taking the preset measurement, however, the predetermined inflation pressure is dynamically adjusted based upon the trended analysis of the most recent blood pressure measurements taken of the patient. To that end, if the trended readings change then the predetermined inflation pressure automatically changes based on the changes to the trended readings. Therefore and if the patient is typically hypotensive, his or her predetermined inflation pressure will be quite a bit lower than the pressure that is required to effectively obtain a reading for a usually hypertensive patient. As should be seen, the advantages to this system are faster and more efficiently taken blood pressure readings with less patient discomfort.

In another version, the workstation will sound or signal an alert to a user if a blood pressure or other physiologic data reading for a selected patient exceeds a predetermined percentage. The basis for the percentage, like the predetermined inflation pressure, is a plurality of previous or trended data readings to which the most current reading is compared. As such, the percentage itself is a constant, but the comparison is based upon the variables of the current readings of a particular patient as well as the changing trend of the patient's readings over time. It is known to provide a typical range of values for a patient in which an alert is sounded if readings exceed either of the range limits. Such a device is limited in that its range remains constant. In the present invention, the range is not constant, but one which can change dynamically based on trended values. If the patient's blood pressure, for example, is higher than "normal", then their acceptable range will include values that are higher than those found in a so-called "normal" range.

Turning to the cited art, Hanna describes a technique that permits a user to identify a specific type of cuff assembly from a plurality of cuff assemblies that are interchangeably connected to a sphygmomanometer. Each of the cuff assemblies include a gas-flow restrictor which allows a pressure measurement made during the deflation phase thereof to identify via correlation the specific cuff assembly. A pair of pressure

transducers automatically obtain pressure measurements and the obtained pressure measurements are used to calculate ratios that are used in order to determine the specific cuff that is attached. This reference does not relate to an apparatus that can perform different pressure measurements on a specific patient in which trended values involving the patient are utilized to determine a predetermined inflation pressure. Clearly, it is understood that if one understands which cuff assembly (i.e., neonatal, adult, child) as in the case of Hanna, then one would arguably be able to define a typical inflation pressure for that cuff that could be applied automatically in an electronic apparatus, for example. However, there are variations between patients, for example, of those wearing the adult cuff and all that Hanna is capable of doing, as presently understood, is to be able to inflate the cuff to a nominal inflation pressure once the type of cuff (adult) has been identified. To that end, if the patient is typically hypotensive (i.e., having blood pressure readings that are typically below 120/80), then this inflation pressure may be too great than that required to take an accurate measurement, resulting in patient discomfort and possible inaccuracies. Likewise, a hypertensive patient (one having readings typically greater than 120/80) would have a fitted cuff inflated to a pressure that is insufficient to perform an accurate reading and require a second inflation using a larger inflation pressure, increasing the time of measurement and also producing patient discomfort. On the other hand, according to the present invention and prior to inflating the cuff, the present workstation utilizes previous readings of the same patient and determines the inflation pressure for the patient based on the previous readings therefor.

Roeher describes a dialysis apparatus that includes a pressure meter as well as a controller in which the monitoring of blood pressure is performed automatically in predetermined time intervals. According to this reference, it is understood that in the course of hemodialysis it is necessary to take blood pressure measurements continuously (i.e., on a periodic schedule). However, there are times when it may not be necessary to take a blood pressure reading. This reference teaches that hypothetical blood pressure readings can be used in lieu of actual readings based upon a statistical comparison of a blood pressure curve for a patient after a predetermined period of time with stored curves of the same type that were determined for the same patient during an earlier time period.

To that end, if the present curve compares favorably with the stored curve(s) – that is, the variation is within some scatter range, then the next scheduled blood pressure reading can be omitted and a previous curve which is most similar to the current curve is used as a basic curve. Though this reference provides teaching into analysis of previous blood pressure data, this reference fails to specify a predetermined inflation pressure based on the status of the patient from previous blood pressure readings.

Halpern et al. describes a workstation that includes a plurality of modules that are contained in or are attachable to the workstation including those for therapy and diagnosis.

Finally, Weiner et al. describes a patient monitoring system that includes at least one patient monitoring device that is linked to a central monitoring station. The Examiner has noted that Weiner's use of having alarms sound if data extends beyond a predetermined range reads upon Applicant's setting of a patient specific percentage as defined in Claim 104. Applicant respectfully disagrees with this simplification. Weiner defines at col 28, lines 17 that the controller can be configured to analyze whether vital signs data is within certain defined nominal ranges and to indicate an alarm condition if the controller detects that a portion of the data is not within the defined ranges. As an example, a range of heart beats between 120 and 50 beats per minute are set as the range wherein the patient monitor will indicate an alarm if the detected heart rate is either greater than 120 or less than 50 beats per minute. The reference notes that alternatively, any other portion of collected vital signs data (including blood pressure data) may be analyzed for alarm conditions, and that defined ranges are variable parameters. However, what is always being set is a set of ranges (a high value and a low value) irrespective of the patient to which the apparatus is attached. Though the apparatus can have the ranges tailored for a specific patient, if one were to move the present workstation between patients, the range for the alerts could be different based on the fact that a percentage is utilized for the patient. Nowhere is there any indication or teaching in this cited reference that comparisons are made between current readings and recently collected readings in which an alert is sounded if the readings exceed a specified percentage. Claim 104 has been amended to clarify the above feature. Support is found at paragraph [0150]. Therefore, it is believed no new matter has been added.

The Examiner has indicated that with regard to Claim 90, the term "trended" as written lends itself to an extremely broad interpretation and therefore the prior art (Hanna and Roeher in combination) adequately cover this claim. Applicant has amended this independent claim to now specify that the predetermined inflation pressure is changed automatically as a result of a comparison of a current blood pressure reading with trended (previous) blood pressure readings of a patient using the cuff. Put another way, a change in the trended blood pressure readings will cause a corresponding change in the predetermined inflation pressure.

As noted, Hanna merely is capable of determining the type of cuff that is being used by an blood pressure measuring apparatus from a plurality of such apparatus. This reference relies upon a plurality of cuffs. While each of the cuffs themselves can be inflated to a predetermined inflation pressure, nowhere is there any teaching of being able to change the predetermined inflation pressure for the single cuff of the present invention and moreover to change the inflation pressure on the basis of trended blood pressure readings. Roeher relates to the use of blood pressure curves/previous blood pressure data, but does not relate to deriving an inflation pressure based upon trended blood pressure readings of a patient.

As noted, Applicant has now amended independent Claim 90 in order to cover the above essential features more clearly and succinctly so as to more clearly point out and describe the present invention. To that end, this claim has been amended to specify that the predetermined inflation pressure is automatically changed based on a change in trended blood pressure readings. As such, the apparatus will permit inflation to a pressure that will enable the device to automatically and successfully obtain a blood pressure measurement the first time, for example, for a hypertensive patient by having sufficient data to realize that a higher than "normal" inflation pressure is necessary in order to successfully obtain a blood pressure reading from the patient. Without this previous knowledge, multiple attempts at obtaining blood pressure would be required. Support is found in the present application; see, for example, paragraph [0150]. Therefore, no new matter has been added.

Because none of the cited prior art includes or suggests any of the features presently cited by Claim 90, as amended, there can be no obviousness under the Statute. Claims 94-103 are believed to be allowable for the same reasons. Reconsideration is respectfully requested.

It is also believed that none of the cited art, alone or in combination, include all of the features of independent Claim 104. That is, none of Hanna, Roeher, Halpern and/or Weiner define a workstation that is programmed to periodically collect physiologic data and sound an alert if collected data exceeds a predetermined percentage. For example, a typical prior art device, such as Weiner, would define an acceptable systolic blood pressure range as between 100 to 150. If the device were put on any patient, this would be the range that would be applied to set alerts irrespective of the status of the patient (i.e., hypotensive, hypertensive) In the present invention, however, setting a predetermined percentage permits hypertensive patients, for example, to have a larger acceptable range of acceptable values, as opposed to a patient having typically lower blood pressure readings. In the former instance, the device is not patient specific, as is the case of Weiner, without additional configuration (resetting the ranges based on the patient). The present device, however, is patient specific as the percentage covers a different range depending on the patient and previous readings. Moreover, the changes are dynamic in that the range of acceptable values changes as the trended data readings change. To that end, it is believed neither of Hanna, Halpern or Roeher teach or describe the above-noted feature and since none of the prior art includes or suggest this recited limitation, there can be no obviousness under the Statute. Claims 105 and 106 are believed to be allowable for the same reasons as Claim 104. Reconsideration is therefore respectfully requested.

In summary and in view of the above amendment, Applicant believes the above-captioned application is now in a condition for allowance and an expedited Notice of Allowability is earnestly solicited.

If the Examiner wishes to expedite disposition of the above-captioned patent application, she is invited to contact Applicant's representative at the telephone number listed below.

It is believed no fee is required for the filing of this response. However, in the event that any additional fees are required, the Director is hereby authorized to charge Deposit Account No. 50-3010 for any additional fees and to charge any overpayments thereto.

Respectfully submitted,

HISCOCK & BARCLAY, LLP

Date: September 18, 2007

Peter J. Bilinski
Reg. No. 35,067
One Park Place
300 South State Street
Syracuse, NY 13202-2078
Tel: (315) 422-2131
Fax: (315) 703-7369